

DISCLOSURE STATEMENT – Human Prescription Drug Manufacturers

(Instructions on reverse)

1. Name of Individual Applicant: (Last / First / Middle)		Present Position:	
2. Address of Individual Applicant: (Number, Street, City, Zip)		Phone Number: () -	
3. Name and Address of Firm:		Phone Number: () -	
4. What are your responsibilities with the firm?			
CHECK APPROPRIATE BOX FOR EACH OF THE FOLLOWING ITEMS If the answer to questions 5 through 8 is "Yes", you must attach a written explanation giving full details for each affirmative response. Failure to provide an explanation will delay processing of your application.		YES	NO
5. Have you had a drug or device manufacturing license, or any professional or vocational license denied, suspended, revoked, or placed on probation, or other disciplinary action taken by this or any other governmental authority?			
6. Have you been associated in business with any individual, sole proprietorship, partnership, corporation, or other entity whose drug or device manufacturing license, or any professional or vocational license, was denied, suspended, revoked, or placed on probation, or other disciplinary action taken by this or any other governmental authority?			
7. Have you ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state, or a local ordinance? You must include all convictions, including those that have been set aside under Penal Code Section 1203.4 (Traffic violations of \$100 or less need not be reported).			
8. Have you ever been addicted to, or treated for the habitual use of, any narcotic, prescription drug, or alcoholic beverage?			

I certify under penalty of perjury under the laws of the State of California to the truth and accuracy of the foregoing. I am also aware that I am bound by the applicable Federal, State and local drug laws and regulations.

Date: _____ Signature: _____

All items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the application being rejected as incomplete. The information will be used to determine qualifications for manufacturing human prescription drugs under the California Health and Safety Code. Application and license information is maintained by the Department of Health Services, Food and Drug Branch, at the address listed below. The information may be transferred to another government agency such as a law enforcement agency if necessary for it to perform its duties. Each individual has the right to review the files or records maintained on her/him by the Department unless the records are identified as confidential information and exempted by Section 1798.3 of the civil code.

INSTRUCTIONS:

(A) The Disclosure Statement Form (EH-53) must be completed and submitted by the following individuals:

1. Every "Facility Operator(s)" identified on line #9 of the Drug Manufacturing License Application (EH-52), as having responsibility over human prescription drug manufacturing operations of the applicant firm, **and...**
2. Those individuals identified on line #23 of the Application (EH-52), who are as follows:
 - a. the five highest ranking Corporate Officers (and/or Directors, if the number of Officers is less than five); **or**
 - b. the listed principal Owner(s), Partner(s) or Business Association Members (up to 5 individuals).

(B) When a new Drug Manufacturing License Application (EH 52) is filed due to a change in ownership, **or** there is a change of a principle individual, partner or corporate officer, as described in (A) above, each **new** individual must complete this Form (EH 53). Please provide the following information on the reverse page:

1. **Applicant's Full Name & Current Position**
2. **Applicant's Home Address & Phone Number**
3. **Company's Name, Address, & Phone Number**
4. **Description of Applicant's Responsibilities at the Company**
5. **Description of any Adverse Actions taken against any License previously or currently held.**
6. **Description of any Association with Individuals or Entities subject to any Adverse Actions.**
7. **Description of any Convictions or No Contest Pleadings of a violation of Law.**
8. **Describe any Addiction to, or Treatment for use of Narcotics, Prescription Drugs, or Alcoholic Beverages.**
9. **Sign & Date**

(C) Attach a listing of your experience in drug manufacturing or related firms. (A resume is acceptable.)

(D) Submit this Disclosure Statement Form (EH 53) with original signatures, and attachments, **along with**...:

1. A COPY of the corresponding Drug Manufacturing License Application (EH 52);
2. A COPY of the drafted check covering the appropriate Drug Manufacturing Licensing fee listed on application form (EH 52);

...TO: (Regular Mail):

CA Department of Health Services
Food and Drug Branch
PO Box 997413, MS-7602
Sacramento, CA 95899-7413

(Overnight Mail):

CA Department of Health Services
Food and Drug Branch
1500 Capitol Avenue, MS-7602
Sacramento, CA 95814

FINGERPRINT LIVE SCAN REQUIREMENT:

Each individual submitting this Disclosure Statement Form (EH-53) must also submit to an Applicant Fingerprint Live Scan. This fingerprint scan is electronically forwarded to the CA Department of Justice (DOJ), who will conduct a criminal history background review of the identified applicant. The Department of Health Services (DHS) will soon make available, a semi-completed REQUEST FOR LIVE SCAN SERVICE form (BCII 8016; in triplicate), that must be taken to a Fingerprint Live Scan operator for processing. The operator will process your fingerprints, collect all applicable fees*, and return a copy this Form for submission to DHS. The results of your background check will be forwarded to DHS for final determination of your firm's Drug Manufacturing License qualifications.

*Note: Separate fingerprint processing fees may be charged by both the Department of Justice, and the Live Scan operator who will collect them accordingly. To find the Live Scan site nearest to you and a listing of fees, go to the CA Attorney General's website at: <http://ag.ca.gov/fingerprints/publications/contact.htm>.